BRIGHT-CHEQ Incubator

Geobacillus stearothermophilus

Operation Manual

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

TABLE OF CONTENTS

The BRIGHT-CHEQ incubator is protected by U.S. Patent 6,455,272. Other patents pending.

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

INTRODUCING THE BRIGHT-CHEQ INCUBATOR

The BRIGHT-CHEQ incubator is a valuable laboratory tool used for the rapid evaluation and automatic documentation of Etigam BRIGHT-CHEQ steam biological indicators (BIs). The incubator monitors BRIGHT-CHEQ BIs during incubation and alerts the user when growth is detected (positive) or when the incubation period has ended without any growth detected (negative).

The Etigam BRIGHT-CHEQ is a self-contained color-change biological indicator consisting of a small plastic culture tube containing an inoculated paper strip and a glass ampoule of growth medium. Upon removal from the sterilizer, the BRIGHT-CHEQ BI is activated by flexing the culture tube in the BRIGHT-CHEQ incubator's crushing cavity to break the media ampoule inside, allowing the growth medium to mix with the paper spore strip. If any spores have survived the sterilization process, the bacteria will grow during incubation and cause the pH indicator dye in the growth medium to change from purple to yellow.

The BRIGHT-CHEQ incubator continuously monitors up to ten independent BRIGHT-CHEQ biological indicators for any color change to yellow during the incubation period. All test results are automatically printed to the attached printer the moment they become available, and the user is alerted to any change in test status by an audible alarm. Because the incubator relies solely on a color change in the biological indicator itself, all test results are verifiable by the user.

The BRIGHT-CHEQ incubator features a touch-sensitive liquid crystal display (LCD) for configuration, report customization, and monitoring the status of each incubation cell. The user can set the current time and date, adjust the incubation time, change display and sound settings, and enter cell-specific test information to be printed on each test report, such as sterilizer number and BI lot number.

The BRIGHT-CHEQ incubator is calibrated to 60ºC ± 2ºC for proper incubation of BRIGHT-CHEQ biological indicators containing spores of *Geobacillus stearothermophilus*. The incubator has a small chamber for the included NIST-traceable thermometer which can be used to easily verify that the unit is maintaining correct temperature.

INSTALLATION

UNPACKING AND INSPECTION

1. Remove all contents from the box and carefully inspect all components for any damage caused in transit. If any damage is observed, notify your Etigam representative immediately.

2. Verify that the following components have been included in the kit:

    •   BRIGHT-CHEQ incubator

    •   BRIGHT-CHEQ 12V power pack – input voltage 110 or 220

    •   NIST Thermometer

    •   Printer kit including printer, manual, 7V power pack (input voltage 110 or 220), plug adapter for power pack (optional), one roll of paper, and one printer ribbon

    •   Serial printer cable

    •   Stylus

    •   BRIGHT-CHEQ record book

    •   BRIGHT-CHEQ Incubator Manual and Etigam BRIGHT-CHEQ Biological Indicator Monitoring System Product Overview

OPERATIONAL PRECAUTIONS

| ⚠	**Use Only as Directed**
	• **Indoor use only.**
	• **Temperatures 5°C to 37°C.**
	• **Altitude < 2000 M.**
	• **Pollution Degree 2.**
	• **Installation Category II.**
	• **Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 37°C.**
	• **Main power supply voltage fluctuations not to exceed ± 10% of the nominal voltage.**
	• **Do not place incubator in drafty areas, near open windows, air conditioning, heating vents, or heat-generating equipment since fluctuating temperatures may affect the incubator temperature.**
	• **Incubator is designed for use with Etigam BRIGHT-CHEQ self-contained biological indicators containing *G. stearothermophilus*. Erroneous results may occur when other biological indicators are used.**

PRINTER SETUP

⚠	**Prior to operating the printer, refer to the warnings and remarks on pages 1-5 and 22 of the printer manual.**

CONNECTING AC POWER

1. Ensure that the power switch on the side of the printer is in the **OFF** position.

2. Insert the small connector from the printer power pack into the matching receptacle in the back of the printer.

3. If a plug adapter for your environment was included with the kit, attach the plug adapter to the printer power pack.

   ⓘ You may have to supply an appropriate plug adapter for your environment if one was not included with the kit.

4. Plug the printer power pack into an outlet.

LOADING THE PRINTER RIBBON CASSETTE

1. To remove the printer cover, grasp the protrusion at the rear of the cover and lift up.

2. Press down on the ribbon cassette while inserting the ribbon between the printing head and platen (see Figure 1). The ribbon cassette will click into place.

3. Wind up the ribbon slack by turning the knob on the left side of the cassette in the direction of the arrow that appears above the knob (see Figure 1).
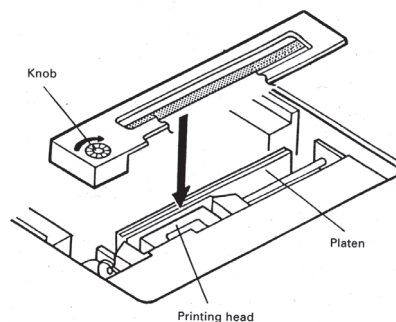
Figure 1. Loading the Printer Ribbon

   ⓘ To remove the ribbon cassette, remove the printer cover and pull up on the cassette where indicated by the word **PULL**.

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

LOADING PAPER

1. To remove the printer cover, grasp the protrusion at the rear of the cover and lift up.

2. If the printer is turned off, switch it on.

3. Press the **SEL** button until the **SEL** light is off.

4. Hold the paper roll such that the paper unwinds towards you from the bottom of the roll.

5. With scissors, cut the end of the paper at an angle towards the roll from right to left (see Figure 2).

Figure 2. End of paper with proper tail for feeding

6. Insert the end of the paper into the slot at the rear of the printing mechanism (see Figure 3) and press the **LF** button until approximately 5 or 6 cm of paper feeds through the mechanism.

7. Pull the black paper holder outward and insert the paper roll (see Figure 3).
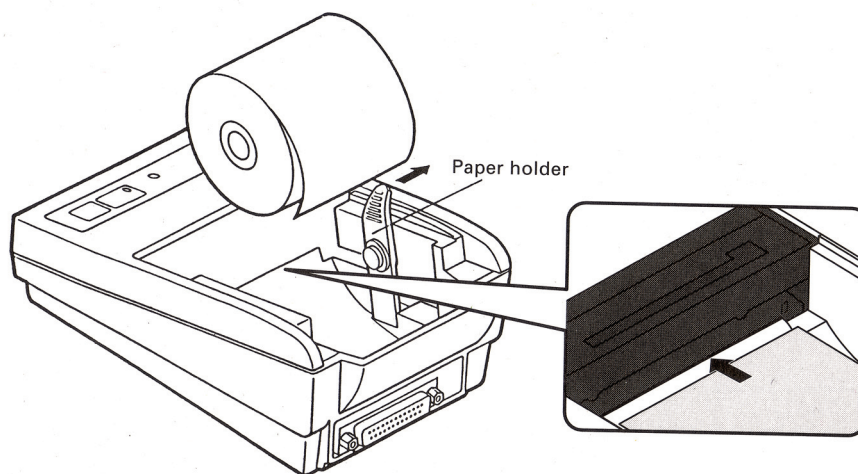
Paper holder

Figure 3. Loading the paper roll

8. Pass the end of the paper through the slot on the printer cover, and mount the cover.

ⓘ To remove the paper roll, remove the printer cover, pull the black paper holder outward, lift the roll, and slowly pull the end of the paper out of the printing mechanism.
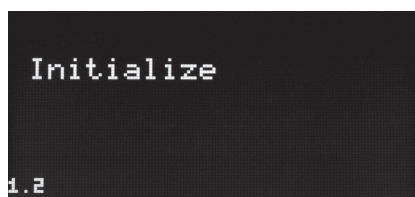
PREPARING TO PRINT

1. Ensure that the printer is plugged in, the ribbon cassette and paper are loaded, and the power switch is in the **ON** position.

2. Press the **SEL** button until the **SEL** light is on.
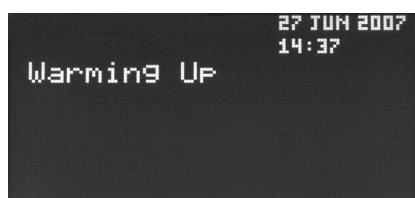
ⓘ The printer is now online and ready to print.

> **Refer to the printer manual for additional printer information and detailed procedures.**
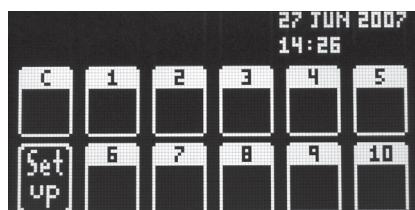
INCUBATOR INSTALLATION

Initialize Screen

Warming Up Screen

Main Menu

1. Follow the *Printer Setup* procedures in this section of the manual to assemble and bring the printer online.

2. Connect the printer to the incubator using the supplied serial printer cable.

3. The incubator power pack (12V) has four plug adapters for international use. Install the appropriate plug adaptor for your environment onto the incubator power pack.

4. Insert the small connector from the incubator power pack into the matching receptacle in the back of the incubator, then plug the power pack into an outlet.

   ⓘ The incubator will turn on and the **Initialize** screen will appear on the LCD indicating that the incubator has started its initialization routine. After initialization, the **Warming Up** screen will appear with a date and time in the upper right hand corner of the display. The status LEDs on the face of the incubator will blink red in succession while the incubator warms up.

5. Place the thermometer into the cell labeled **T**.

6. Wait for the status LEDs on the incubator to turn off and for the **Main Menu** screen to appear.

7. Configure the incubator using the procedures in the *Configuration - Global Settings* and *Configuration - Cell Settings* sections of this manual.

👉 **Note: The incubator is designed for continuous use and does not have a power switch.**

CONFIGURATION

GLOBAL SETTINGS

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

CONFIGURING THE INCUBATOR

The BRIGHT-CHEQ incubator must be properly configured prior to use. The following options affect the overall operation of the incubator (items not marked as optional are required and must be configured prior to using the device):

- **Incubation Time** - the length of the incubation period. Any BRIGHT-CHEQ BI that has remained purple for this duration will be considered negative by the incubator. This setting affects all incubation cells.

- **Time** - the current time in 12-hour or 24-hour format.

- **Date** - the current date.

- **Display Configuration** (optional) - The contrast of the LCD can be adjusted for optimal viewing. Additionally, the display can be inverted such that light items appear dark and dark items appear light.

- **Sound Configuration** (optional) - The input confirmation sound and test completion alarm can be disabled. Additionally, the alarm that sounds when a BRIGHT-CHEQ BI is removed from an incubation cell can be disabled.

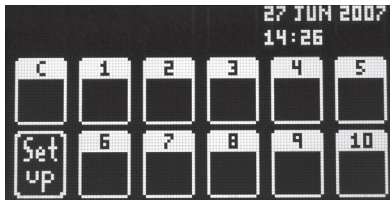## ADJUSTING INCUBATION TIME
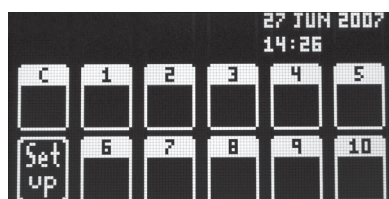
Main Menu
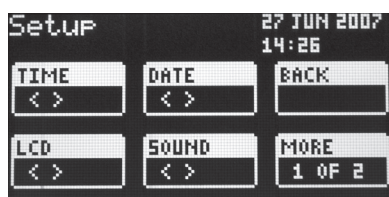
Setup Menu

Setup Menu Page 2

1. From the **Main Menu**, touch the **SET-UP** key to enter the **Setup Menu**.

2. From the **Setup Menu**, touch the **MORE** key to enter **Setup Menu Page 2**.

3. Touch the **INC TIME** key to adjust the duration of the incubation period. Using the key pad that appears on-screen, enter the incubation period duration in hours. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Setup Menu**, touch the **ENTER** key. To return to the **Setup Menu** without adjusting the incubation time, touch the **CANCL** button.

4. If configuration is complete, touch the **BACK** key to return to the **Main Menu**.

   ⓘ Touching the **BACK** key from either the **Setup Menu** or **Setup Menu Page 2** will return to the Main Menu.
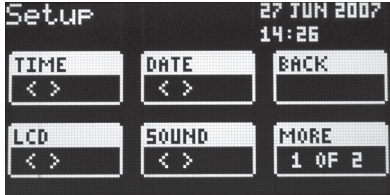
The default incubation time setting is 24 hours. Etigam recommends a reduced incubation time of 10 hours based on our study using the FDA reduced incubation time (RIT) protocol.
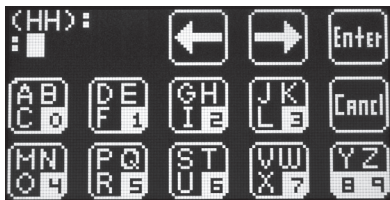
SETTING THE TIME

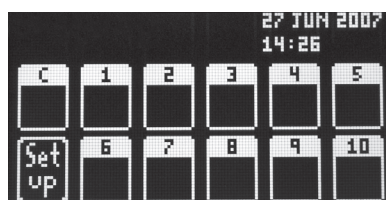**Main Menu**

Setup Menu
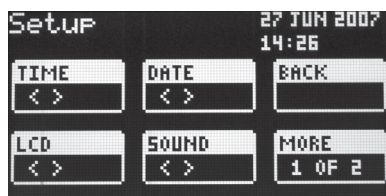
Time Menu

Hour Menu

1. From the **Main Menu**, touch the **SET-UP** key to enter the **Setup Menu**.

2. From the **Setup Menu**, touch the **TIME** key to enter the **Time Menu**.

3. To set the hour, touch the **HOUR** key. Using the key pad that appears on-screen, enter the correct hour. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Time Menu**, touch the **ENTER** key. To return to the **Time Menu** without modifying the hour, touch the **CANCL** key.

4. To set minutes, touch the **MINUTE** key. Using the key pad that appears on-screen, enter the correct minutes. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Time Menu**, touch the **ENTER** key. To return to the **Time Menu** without modifying the minutes, touch the **CANCL** key.

5. Choose between 12-hour and 24-hour clock display by touching the **12/24** toggle key until the desired selection appears.

6. If the 12-hour clock display has been selected, set AM/PM by touching the **AM/PM** toggle key until the desired selection appears on the screen. If the 24-hour clock display is selected, the **AM/PM** key will be disabled.

7. Touch the **BACK** key to return to the **Setup Menu**.

8. If configuration is complete, touch the **BACK** key to return to the **Main Menu**.

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

SETTING THE DATE

Main Menu

Setup Menu

Date Menu

Day Menu

1. From the **Main Menu**, touch the **SET-UP** key to enter the **Setup Menu**.

2. From the **Setup Menu**, touch the **DATE** key to enter the **Date Menu**.

3. To set the day, touch the **DAY** key. Using the keypad that appears on-screen, enter the correct day. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Date Menu**, touch the **ENTER** key. To return to the **Date Menu** without modifying the day, touch the **CANCL** key.

4. To set the month, touch the **MONTH** key. Using the key pad that appears on-screen, enter the correct month. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Date Menu**, touch the **ENTER** key. To return to the **Date Menu** without modifying the month, touch the **CANCL** key.

5. To set the year, touch the **YEAR** key. Using the keypad that appears on-screen, enter the last two digits of the correct year. Use the **ARROW** keys to move the cursor position, if necessary.To save and return to the **Date Menu**, touch the **ENTER** key. To return to the **Date Menu** without modifying the year, touch the **CANCL** key.

6. Touch the **BACK** key to return to the **Setup Menu**.

7. If configuration is complete, touch the **BACK** key to return to the **Main Menu**.
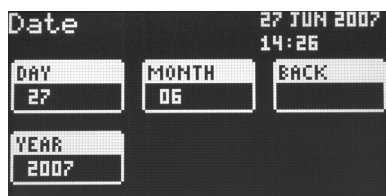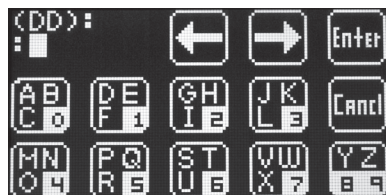
DISPLAY CONFIGURATION

Main Menu
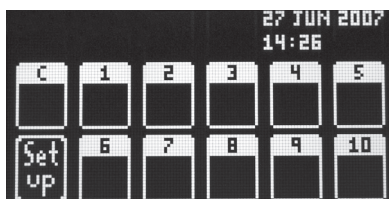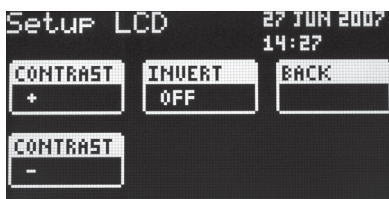
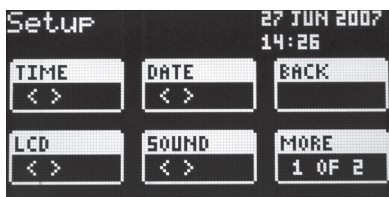**Setup Menu**

Setup LCD Menu
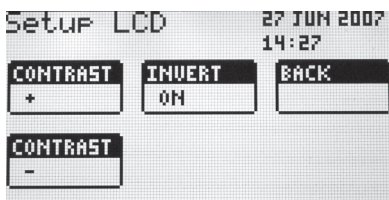
Inverse Setup LCD Menu

1. From the **Main Menu**, touch the **SET-UP** key to enter the **Setup Menu**.

2. From the **Setup Menu**, touch the **LCD** key to enter the **Setup LCD Menu**.

3. To increase the display contrast, touch the **CONTRAST +** key repeatedly until the desired setting is achieved.

4. To decrease the display contrast, touch the **CONTRAST −** key repeatedly until the desired setting is achieved.

5. To invert the color scheme of the screen, touch the **INVERT** toggle key until the desired setting is achieved.

6. Touch the **BACK** key to return to the **Setup Menu**.

7. If configuration is complete, touch the **BACK** key to return to the **Main Menu**.

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System
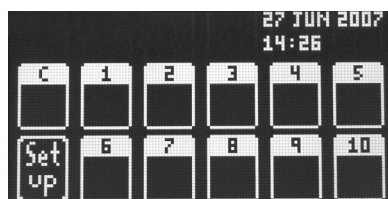
SOUND CONFIGURATION
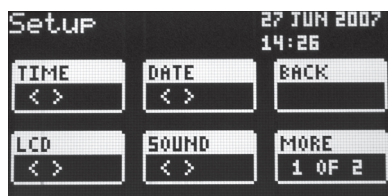

Main Menu
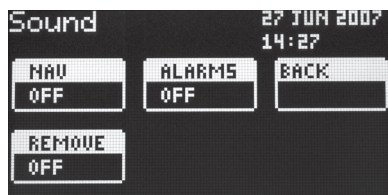
Setup Menu

Sound Menu

1. From the **Main Menu**, touch the **SET-UP** key to enter the **Setup Menu.**

2. From the **Setup Menu**, touch the **SOUND** key to enter the **Sound Menu**.

3. To turn key-touch confirmation sound on or off, touch the **NAV** toggle key until the desired setting appears. When **NAV** is on, a sound will play each time a key is touched on the screen.

4. To enable or disable the alarm that sounds when a BI has turned yellow or has remained purple for the entire incubation period, touch the **ALARMS** toggle key until the desired setting appears.

5. To enable or disable the alarm that sounds when a BI is removed from an incubation cell, touch the **REMOVE** toggle key until the desired setting appears.

6. Touch the **BACK** key to return to the **Setup Menu.**

7. If configuration is complete, touch the **BACK** key to return to the **Main Menu**.

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System
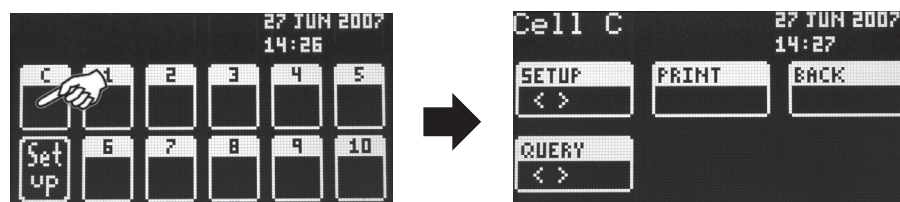
CONFIGURATION

CELL SETTINGS

CONFIGURING INDIVIDUAL CELLS

Each incubation cell can be independently configured by touching its corresponding key on the **Main Menu**. There are ten incubation cells numbered **1** through **10**, and one positive control incubation cell marked by the letter **C**.

To bring up the Cell Menu for any incubation cell, touch the corresponding key on the Main Menu.

Cell Menu

Each incubation cell should be properly configured prior to use, and as needed over time. The following parameters can be configured for each individual incubation cell:

- **Etigam BRIGHT-CHEQ BI Lot Number** - the lot number of the BRIGHT-CHEQ BI being tested.

- **Sterilization Cycle Number** - the identification number of the cycle in which the BRIGHT-CHEQ BI was exposed.

- **Operator Initials** - the initials/identification number of the operator responsible for the test in the selected cell.

- **Sterilization Cycle Type** - the type of cycle to which the BRIGHT-CHEQ BI was exposed.

- **Sterilization Temperature** - the temperature of the cycle to which the BRIGHT-CHEQ BI was exposed.

- **Sterilization Exposure Time** - the exposure time of the cycle to which the BRIGHT-CHEQ BI was exposed.

> **The configuration values entered for each incubation cell appear on test report printouts only, and have no affect on the operation of the incubator.**
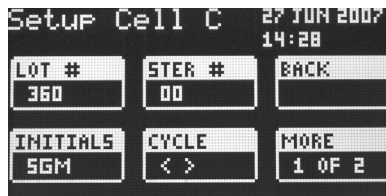
> **As a user convenience, individual cell configurations do not reset upon test completion. The settings entered for each cell will remain active until they are changed by the operator.**
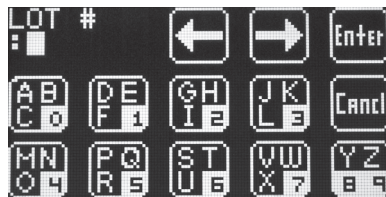
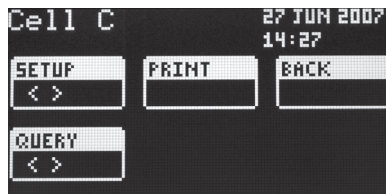## SETTING THE ETIGAM BRIGHT-CHEQ BI LOT NUMBER
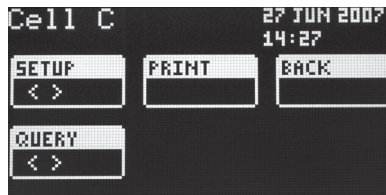
Cell Menu

Setup Cell Menu

Lot # Menu

1. From the **Main Menu**, touch the key representing the desired cell to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **SETUP** key to enter the **Setup Cell Menu**.

3. From the **Setup Cell Menu**, touch the **LOT#** key to set the Etigam BRIGHT-CHEQ lot number. Enter the three digit numerical portion of the Etigam BRIGHT-CHEQ lot number (the "S-" lot number prefix should not be entered). Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Setup Cell Menu**, touch the **ENTER** key. To return to the **Setup Cell Menu** without modifying the Etigam BRIGHT-CHEQ lot number, touch the **CANCL** key.

4. If cell configuration is complete, touch the **BACK** key to return to the **Cell Menu,** then touch the **BACK** key again to return to the **Main Menu**.

SETTING THE STERILIZATION CYCLE NUMBER

Cell Menu

Setup Cell Menu

Sterilizer # Menu

1. From the **Main Menu**, touch the key representing the desired cell to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **SETUP** key to enter the **Setup Cell Menu**.

3. From the **Setup Cell Menu**, touch the **STER#** key to set the sterilization cycle number. Using the keypad that appears on-screen, enter up to three alphanumeric characters representing the sterilization cycle number. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Setup Cell Menu**, touch the **ENTER** key. To return to the **Setup Cell Menu** without modifying the sterilization cycle number, touch the **CANCL** key.

4. If cell configuration is complete, touch the **BACK** key to return to the **Cell Menu,** then touch the **BACK** key again to return to the **Main Menu**.

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

SETTING OPERATOR INITIALS
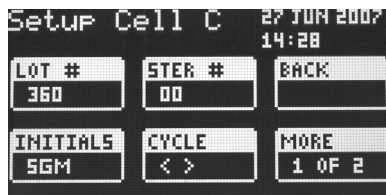
Cell Menu

Setup Cell Menu

Operator Initials Menu

1. From the **Main Menu**, touch the key representing the desired cell to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **SETUP** key to enter the **Setup Cell Menu**.

3. From the **Setup Cell Menu**, touch the **INITIALS** key to enter the operator's initials/identification. Using the key pad that appears on-screen, enter up to three alphanumeric characters representing the operator's initials. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Setup Cell Menu**, touch the **ENTER** key. To return to the **Setup Cell Menu** without saving, touch the **CANCL** key.

4. If cell configuration is complete, touch the **BACK** key to return to the **Cell Menu,** then touch the **BACK** key again to return to the **Main Menu**.
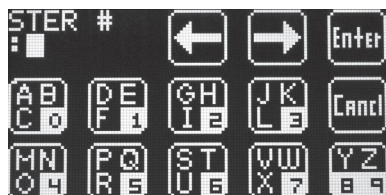
SETTING THE STERILIZATION CYCLE TYPE, STERILIZATION TEMPERATURE, AND STERILIZATION EXPOSURE TIME

Cell Menu

Setup Cell Menu
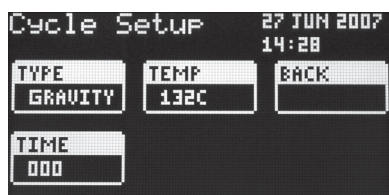
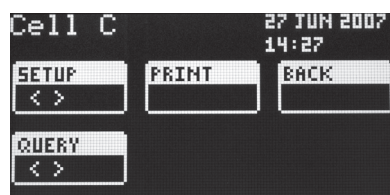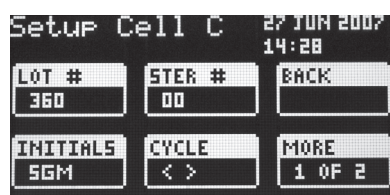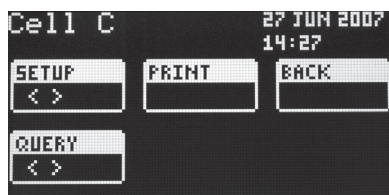**Cycle Setup Menu**

1. From the **Main Menu**, touch the key representing the desired cell to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **SETUP** key to enter the **Setup Cell Menu**.

3. From the **Setup Cell Menu**, touch the **CYCLE** key to enter the **Cycle Setup Menu**.

4. To set the cycle type, touch the **TYPE** toggle key until the desired setting appears.

Cycle Type Options
Prevac
Flash
Express
Gravity

5. To set the cycle exposure time, touch the **TIME** key. Using the keypad that appears on-screen, enter the cycle exposure time in minutes. Use the **ARROW** keys to move the cursor position, if necessary. To save and return to the **Cycle Setup Menu**, touch the **ENTER** key. To return to the **Cycle Setup Menu** without saving, touch the **CANCL** key.

6. To set the cycle exposure temperature, touch the **TEMP** toggle key until the desired setting appears.

Cycle Temp. (°C) Options	
121°	132°
134°	135°

7. Touch the **BACK** key to return to the **Setup Cell Menu**.

8. If cell configuration is complete, touch the **BACK** key to return to the **Cell Menu**, then touch the **BACK** key again to return to the **Main Menu**.
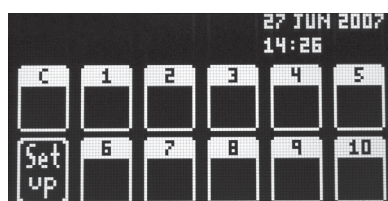
Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

DUPLICATING CELL CONFIGURATION

Main Menu
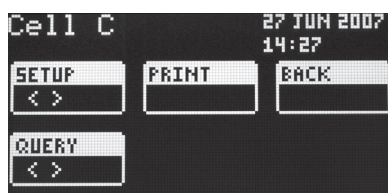
Cell Menu

Setup Cell Menu
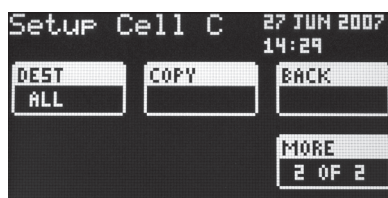
Setup Cell Menu Page 2

1. From the **Main Menu**, touch the key representing the cell that configuration settings will be *copied from* to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **SETUP** key to enter the **Setup Cell Menu**.

3. Touch the **MORE** key to advance to **Setup Cell Menu Page 2**.

4. To select the destination cell(s) to which the configuration settings will be copied, touch the **DEST** toggle key until the desired selection appears.

   ⓘ The **DEST** key toggles between incubation cells represented by numbers **1** through **10**, the positive control cell represented by the word **CTRL**, and all eleven cells represented by the word **ALL**.

Destination Cell Options											
ALL	1	2	3	4	5	6	7	8	9	10	CTRL

5. Touch the **COPY** key to copy the information to the selected cell(s).

6. Touch the **BACK** key to return to the **Cell Menu**.

7. Touch the **BACK** key to return to the **Main Menu**.

8. To verify that configuration settings were copied successfully, query each cell that parameters were copied to. Refer to the *Viewing Cell Status* and *Printing* procedures in the *Operation* section of this manual.

9. Repeat this procedure for other cells as necessary.

   ⓘ Touching the **BACK** key from either the **Setup Cell Menu** or **Setup Cell Menu Page 2** will return to the **Cell Menu**.

OPERATION

TESTING ETIGAM BRIGHT-CHEQ BIOLOGICAL INDICATORS

1. To activate a Etigam BRIGHT-CHEQ BI, place it into the BRIGHT-CHEQ incubator crushing cavity (Figure 1) and pull it forward until the glass ampoule inside breaks, releasing the purple growth media.

2. Place one unexposed, activated BI into the positive control cell labeled **C** (Figure 1). A yellow BI is the desired result for the positive control. A positive control is to be used anytime a load is being verified or at least once per day.

3. Activate all processed Etigam BRIGHT-CHEQ BIs and place them into the incubation cells numbered **1** through **10** (Figure 1).

Positive control cell
Incubation cells
BI crushing cavity
Status indicator LEDs
Orange = unit in test
Green = no growth
Red = growth
Touch-sensitive user interface
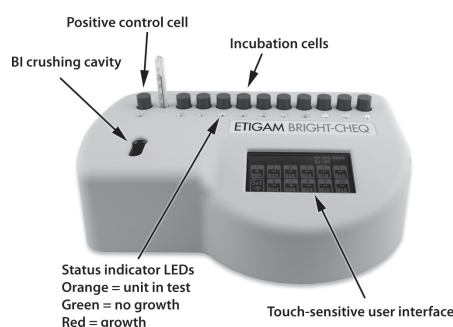
Figure 1. BRIGHT-CHEQ incubator

ⓘ When a Etigam BRIGHT-CHEQ BI is placed into a cell, the status LED (Figure 1) in front of the cell will illuminate amber indicating that the incubator has recognized the BI. The corresponding key on the LCD **Main Menu** (Figure 2) will display the word **TEST** and the number of whole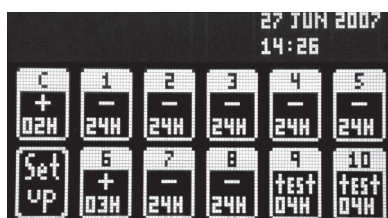 hours that the test has been in progress (Figure 3). (e.g. if a test has been in progress for four and a half hours, the display will read **04H**).

Figure 2. Main Menu with positive, negative, and testing samples

Cell Number
Test status
Number of whole hours test has been running
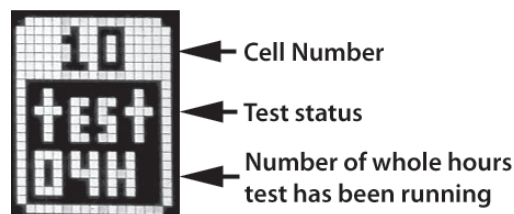
Figure 3. Cell key

Table 1. Status LEDs color descriptions

Status LEDs Color Descriptions	
Off	Cell Empty
Amber	Test in Progress
Blinking Amber	Test in Progress, BRIGHT-CHEQ removed (max. 10 seconds)
Red	Test Positive
Blinking Red	Test Positive, BRIGHT-CHEQ removed (max. 10 seconds)
Green	Test Negative
Blinking Green	Test Negative, BRIGHT-CHEQ removed (max. 10 seconds)
All Colors Cycling	Invalid Test, BRIGHT-CHEQ must be removed

☞ **If the incubator does not recognize a BRIGHT-CHEQ BI that has been placed into an incubation cell, give the BI a quarter turn or try the BI in a different cell. Use only Etigam BRIGHT-CHEQ biological indicators.**

Refer to *Appendix A. Troubleshooting*.

ⓘ For viewing purposes, a Etigam BRIGHT-CHEQ BI can be removed from the incubator for up to 10 seconds. When a BI is removed from a cell, the status LED in front of the cell will start blinking (see Table 1). If configured, an alarm will sound after five seconds. The Etigam BRIGHT-CHEQ BI must be placed back into the cell before the alarm stops in five more seconds or the test will be cancelled and the cell will be reset. Refer to the *Sound Configuration* procedure in the *Configuration - Global Settings* section of this manual for instructions to disable or enable the BI removal alarm.

> 👉 **If a BRIGHT-CHEQ BI is removed from an incubation cell, it must be returned within 10 seconds or the cell will be reset and the current test cannot be resumed.**

4. If a Etigam BRIGHT-CHEQ BI has turned yellow (positive) at any time during the incubation period, the status LED in front of the incubation cell will turn red and a **+** will appear in place of the word **TEST** in the corresponding key on the **Main Menu**. An audible alarm will sound (if configured) and the test results will be printed automatically.

   a. To cancel the audible alarm, touch anywhere on the screen.

   b. Remove the Etigam BRIGHT-CHEQ BI from the cell.

   c. If configured, the BI removal alarm will sound after the BI has been removed for five seconds.

   d. Visually inspect the Etigam BRIGHT-CHEQ BI for yellow color.

   e. If the result is confirmed, act immediately on a positive test and follow appropriate institution procedures.

5. If a Etigam BRIGHT-CHEQ BI has remained purple for the duration of the incubation period, the status LED in front of the incubation cell will turn green and a **-** will appear in place of the word **TEST** in the corresponding key on the **Main Menu**. An audible alarm will sound (if configured) and test results will be printed automatically.

   a. To cancel the audible alarm, touch anywhere on the screen.

   b. Remove the Etigam BRIGHT-CHEQ BI from the cell.

   c. If configured, the BI removal alarm will sound after the BI has been removed for five seconds.

   d. Visually inspect the Etigam BRIGHT-CHEQ BI for purple color.

   e. If the result is confirmed, it is an indication that the spores were killed by the sterilization process.

> 👉 **All test results MUST be visually confirmed by the operator.**

> 👉 **If there is a problem printing, such as the printer not being online or out of paper, resolve the problem and print the test results manually. See the *Printing* procedure in this section of the manual.**

6. Upon test completion, the easy-to-peel Etigam BRIGHT-CHEQ BI unit label can be removed from the BI and affixed to the printed results. The BRIGHT-CHEQ Record Book may be used to catalogue test results (see below).

USING THE BRIGHT-CHEQ RECORD BOOK

The BRIGHT-CHEQ Record Book can be used to catalogue Etigam BRIGHT-CHEQ BI test reports.

1. Peel the label from the tested Etigam BRIGHT-CHEQ BI and affix to the bottom of the printed test report.

2. Fold and insert the test report into the BRIGHT-CHEQ Record Book.

PRINTING

The BRIGHT-CHEQ printer will automatically print results when a Etigam BRIGHT-CHEQ turns yellow during the incubation period, or if a Etigam BRIGHT-CHEQ BI remains purple at the conclusion of the incubation period. The following information will be printed: cell number, the status of the cell (testing, positive, or negative), start time and date, duration of the test, and selected information entered by the operator.
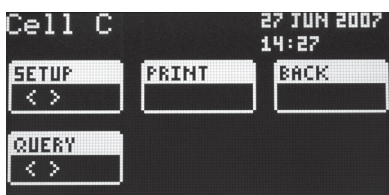
> **Refer to the *Printer Setup* procedures in the *Installation* section of this manual for paper and ribbon cassette loading instructions.**
>
> **Refer to *Appendix A. Troubleshooting* for potential solutions to many printing problems.**

To print a test report manually during a test in progress or at the completion of a test, use the following procedure:
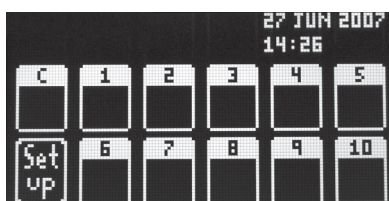
Main Menu

Cell Menu

Printout

1. From the **Main Menu**, touch the key representing the desired cell to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **PRINT** key.

   ⓘ A report for the selected cell will be sent to the printer, including cycle type (Type of Test), the start time and date (ST), the amount of time that the test has been running (TT), the cell number (Cell#), the status of the current test (BI Result: TESTING | + | -), the Etigam BRIGHT-CHEQ BI lot number (Lot #), the sterilizer number (Sterilizer #), blank lines for load identification (Load), and the operator initials (User ID).

3. Touch the **BACK** key to return to the Main Menu.

> **When the printer is nearly out of paper, the SEL light will blink in 1/2 second intervals and printing will be suspended. Replace the paper roll and press the SEL button twice.**

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

OPERATION

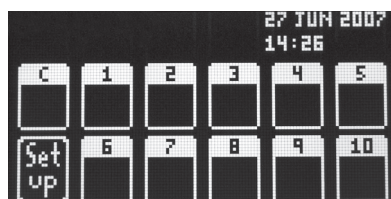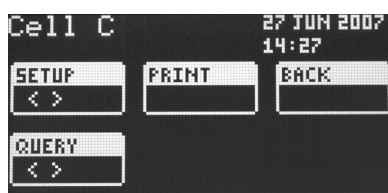### VIEWING CELL STATUS

Main Menu

Cell Menu
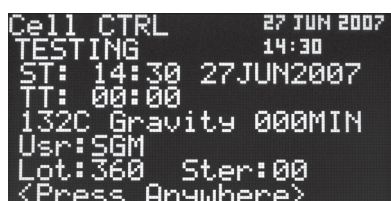
Query Screen

1. From the **Main Menu**, touch the key representing the cell to be viewed to enter its **Cell Menu**.

2. From the **Cell Menu**, touch the **QUERY** key.

   ⓘ The status of the cell will appear, including the cell number, the status of the current test (TESTING|+|-), the start time and date (ST), the amount of time that the test has been running (TT), the cycle type and exposure time, the operator initials (Usr), the Etigam BRIGHT-CHEQ BI lot number (Lot), and the sterilizer number (Ster).

3. Touch anywhere on the screen to return to the **Cell Menu**.

3. Touch the **BACK** key to return to the Main Menu.

POWER FAILURE RECOVERY

Power Interrupt Printout

If the BRIGHT-CHEQ incubator loses power, any test in progress will be saved and upon power return the unit will resume incubation and monitoring. The unit will automatically adjust incubation time to make up for the duration of the power loss. A printout will be generated indicating the time that the power failure occurred and the time that power was returned.

MAINTENANCE AND WARRANTY

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

CLEANING

⚠	• **Unplug the incubator before performing any cleaning.**
	• **Do not immerse the unit in any liquid.**

To clean the outside of the unit, wipe with a cloth dampened with isopropyl alcohol.

To clean the incubation cells, use a cotton swab dampened with isopropyl alcohol.

SERVICE AND REPAIR

Service and repair for the BRIGHT-CHEQ incubator is available from Etigam.

This unit is pre-calibrated by the manufacturer and is not field serviceable.

WARRANTY

Etigam warrants that if a product manufactured by Etigam and sold within the continental United States or Canada proves to be defective in material or construction, Etigam will provide you, without charge, for a period of ninety (90) days, the labor,
and a period of one (1) year, the parts, necessary to remedy any such defect. Outside the continental United States and Canada, the warranty period shall commence either six (6) months following the date the product is sold by Etigam or on the date it is purchased by the original retail consumer, whichever date occurs first. All warranty inspections and repairs must be performed by and parts obtained from an authorized Etigam dealer or Etigam.
The name of the authorized Etigam dealer nearest you may be obtained by calling
+31 55 5211721 or writing to:

ETIGAM BV
Prinsenweide 30,
7317 BB Apeldoorn
The Netherlands
Fax: +31 55 5223931
E-mail: info@etigam.nl
Internet: www.etigam.nl

Etigam sole obligation with respect to its product shall be to repair or replace the product. Under no circumstances shall it be liable for incidental or consequential damage.

THE WARRANTY STATED HEREIN IS THE SOLE WARRANTY APPLICAL TO ETIGAM BRIGHT-CHEQ PRODUCTS. ETIGAM EXPRESSY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR USE.

APPENDICES

BRIGHT-CHEQ INCUBATOR TROUBLESHOOTING

Problem	Solution
Incubator never completes warm up stage.	The incubator can take up to 90 minutes to warm up. If the incubator has been on for over 90 minutes and is still warming up, it may need to be moved to a warmer location away from cold drafts.
Incubator does not recognize inserted BI.	Only Etigam BRIGHT-CHEQ biological indicators will work in the BRIGHT-CHEQ incubator. If a BRIGHT-CHEQ BI is not recognized by an incubation cell, give the BI a quarter turn. If the BRIGHT-CHEQ BI is still not recognized, try placing the BI into a different incubation cell.
Touch-screen becomes unresponsive (freezes).	Unplug the incubator from the power supply for five seconds, then return power. The incubator should recover and continue any test in progress. A power failure acknowledgement will be printed.

PRINTER TROUBLESHOOTING

Problem	Solution
Printer will not print; **SEL** light is on.	Verify that the data cable is connected properly to both the printer and the BRIGHT-CHEQ incubator.
Printer will not print, **SEL** light is off.	Press the **SEL** button until the **SEL** light comes on, indicating that the printer is online and ready to print.
Printer will not print; **SEL** light blinks at 1/2 second intervals.	The printer is nearly out of paper. Replace the paper roll and press the **SEL** button twice.
Printer will not print; **SEL** light blinks at 1/4 second intervals.	A mechanical problem such as a paper jam is preventing the printer from printing. Fix the problem (e.g. clear paper jam and reload the paper) and press the **SEL** button twice.
Printer will not print; **SEL** and **POWER** lights blink simultaneously at 1/10 second intervals.	Turn the printer off and contact Etigam.
Print is light and/or difficult to read.	Replace the ribbon cassette.
LF button does not work.	The **LF** button does not work when the printer is online. Press the **SEL** button until the **SEL** light turns off.

CONSUMABLES

Etigam BRIGHT-CHEQ Biological Indicators	Reorder #
BRIGHT-CHEQ for Steam, Population 10^5	BC-S5
BRIGHT-CHEQ for Steam, Population 10^6	BC-S6
BRIGHT-CHEQ INCUBATOR	BC-INC

Printer Supplies (Citizen CBM-910 Type II)	
Printer consumables can be ordered from many office supply and point-of-sale retailers.	
Printer Ribbon	Mfg. Part Number: IR-91P
Paper	Specifications: Plain paper, 2 ply, or 3 ply Paper Thickness: 0.13 mm or less Roll Diameter (max): 60 or 80 mm Roll Width: 57.5 ± 0.5 mm Core Inner Diameter: 12 ± 1 mm Core Outer Diameter: 18 ± 1 mm

BRIGHT-CHEQ Record Book	Reorder #
Record Book (13 sleeves included)	9201
Record Book Sleeves (package of 13)	9202

ACCESSORIES

BRIGHT-CHEQ Incubator Accessories	Reorder #
BRIGHT-CHEQ Stylus	9054
BRIGHT-CHEQ Thermometer	I1470
BRIGHT-CHEQ Power Supply	P3-1000
BRIGHT-CHEQ Printer (Citizen CBM-910 Type II)	US: PTR/PPUS UK: PTR/PPUK Australia: PTR/PPAUS European: PTR/PPEUR
BRIGHT-CHEQ Printer Cable	9055

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

SPECIFICATIONS

BRIGHT-CHEQ Incubator		
Overall Dimensions	Width	8.5 in (21.5 cm)
	Height	2.4 in (6.1 cm)
	Depth	6.9 in (17.5 cm)
	Weight	2.5 lbs (1.13 kg)
Well Dimensions	Number	11
	Diameter	0.433 in (1.1 cm)
	Depth	1.6 in (4.0 cm)
Thermometer Cell Dimensions	Number	1
	Diameter	0.276 (0.7 cm)
	Depth	1.6 in (4.0 cm)
Electrical Ratings	Volts	12VDC
	Watts	18W
	Amps	1500 mA
Operating Range	Temperature	60 ± 2°C

BRIGHT-CHEQ Incubator Power Pack, Catalog Number P3-1000	
Rated Input Voltage	100 V – 240 V AC
Input Voltage Range	90 V – 264 V AC
Rated Frequency	50-60 Hz
Rated Input Current	600 mA RMS max.
Output Voltage	12 VDC at 1.5A
Output Minimum Current	0A
Safety Approvals	UL/cUL, CE, GS
RoHS Compliant	Yes
Storage Temperature	-10°C ~ +70°C
Storage Humidity	10 ~ 90%
Operating Temperature	0°C ~ +40°C
Operating Relative Humidity	20 ~ 80%

Thermometer, Catalog Number I1470	
Rated	10° - 70°C
Total Length	3 inches (76 ± 2 mm)
Glass Type	Spirit Filled
Stem Diameter	.26 ± .02 inches (6 – 7 mm)
Subdivisions	1° C
Accuracy	± 0.5° C
Numbering	10, 20, 30, 40, 50, 60, 70° C
Special Markings	Arrows at 37° C & 60° C

Etigam BRIGHT-CHEQ Biological Indicator Monitoring System

ETIGAM